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10/664,213	09/16/2003	Hassan Mostafavi	005513P021	3361

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3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,213	MOSTAFAVI ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) *17-48 and 59-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 49-58, and 62-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/15/07, 1/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 4/7/08 is acknowledged. The traversal is on the ground(s) that Groups I and II are not mutually exclusive, Groups II and V are not mutually exclusive, and Groups I and V are not mutually exclusive. This is not found persuasive because:

In regards to Groups I and II, a method of adjusting a position of a target volume within the body is considered to be mutually exclusive from a method of determining coordinates of markers. Furthermore, applicant argues that claims 1 and 17 are "not necessarily" mutually exclusive. Therefore, they could in fact be mutually exclusive.

In regards to Groups II and V, a method of adjusting a position of a target volume within the body is considered to be mutually exclusive from a method of estimating an adjustment to a body and a treatment beam based on a rigidity of the target and a number of visible markers in the image. Furthermore, applicant argues that claims 17 and 31 are "not necessarily" mutually exclusive. Therefore, they could in fact be mutually exclusive.

In regards to Groups I and V, a method of determining coordinates of markers is considered to be mutually exclusive from a method of estimating an adjustment to a body and a treatment beam based on a rigidity of the target and a number of visible markers in the image. Furthermore, applicant argues that claims 1 and 31 are "not necessarily" mutually exclusive. Therefore, they could in fact be mutually exclusive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-48, and 59-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/7/08.

Claim Objections

Claims 4, 10-12, 55-57, 67, 70, 72, and 80-81 are objected to because of the following informalities: In claim 4, it is unclear what the terms KV and MV refer to, these should be defined. In claim 10, the word "identify" should be changed to "identifying". In claim 11, on line 1, "claim10" should be "claim 10". In claim 12, insert "wherein" after "method of claim 6,". In claim 55, the grammar is confusing. The term "a same imager" is awkward. In claims 56 and 57, the word "marker" is misspelled. In claim 67, 70, and 72, the term "MLC" should be defined. Claim 80 is a duplicate of claim 79.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 49-58, and 62-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-21, 24, and 31-43 of copending Application No. 10/664308. Although the conflicting claims are not identical, they are not patentably distinct from each other because determining the coordinates of the markers with respect to the beam isocenters is an obvious modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 49-53 and 63-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The wording of claim 12 is confusing, in particular the term "falsely identifying". From applicant's specification, it

does not appear that markers are being identified at all, and that these are other objects in the image which are not markers. The claim should be reworded to better reflect applicant's intention as to this aspect of the invention. In claim 49, the claim language attempts to define structure in terms of an unclaimed element such as the first and second beam isocenter. It is unclear as to how one can determine the coordinates relative to the isocenter, if the first and second beam source each having an isocenter is not claimed. In claims 63-65, 68, and 73, the term "rigidity of the target" and "the target is rigid" are unclear. It is not clear if this term refers to the physical properties of a target, or if this term is somehow related to calculating a "rigid body transform", such as described in claim 15. The same applies to the term "deformable" in claims 74 and 75.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7, 13-14, 16, 49-58, 62, and 76-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461).

Mate et al. show a guided radiation therapy system. The radiation delivery source can be a linear accelerator, or any other type of radiation therapy device ([0034]). The radiation device has a machine isocenter associated with it. This is the isocenter of the radiation beam ([0035]). A plurality of markers are positioned in the target to mark the actual location of the target in the body. These markers define a target isocenter. The position and orientation of each marker is obtained and used to determine the precise location of the target isocenter ([0036]-[0037]). The markers can be implanted in the patient, and delivered by an applicator needle ([0041]). The actual position of the target isocenter is compared to the position of the machine isocenter, and if they are spatially misaligned, the target can be moved relative to the machine isocenter. Once the target isocenter and machine isocenter are coincident, the radiation treatment is applied ([0039]). Determining the position manually would be a well known and obvious modification to one of ordinary skill in the art. Mate et al. fail to show using more than one imaging modality.

Cosman discloses a surgical positioning system. Cosman teaches that X-ray imaging can be used to further refine the positioning of the isocenter. The X-ray images can aid in determining the position of markers within the body. The use of X-ray

imaging further improves the accuracy of the alignment ([0064]-[0069]). Furthermore, the same imaging modality could be used. Cosman teaches the use of preoperative CT scanning ([0064]) and the use of interoperative CT scanning as well ([0065]). Cosman also teaches that both the treatment machine and the patient can be moved to accomplish desired positional relationships ([0024]). The treatment machine is rotatable ([0025]). A multileaf collimator or any other type of known collimator can be used as well ([0026]). The angle and shape of the treatment beam can be controlled ([0043]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a second imaging system to align the patient and the treatment beam as taught by Cosman in the system of Mate et al. The use of a second imaging system will increase the accuracy of the alignment.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) as applied to claim 1 above, and further in view of Mansfield et al. (US 7227925).

Mansfield et al. disclose a gantry mounted stereoscopic imaging system. Mansfield et al. teach the use of kV and MV imaging in a radiation treatment system (column 7, line 49-column 8, line 63).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used kV and MV imaging as taught by Mansfield et al., as a substitute for the second imaging modality (X-ray imaging) of Cosman. KV and MV imaging are specific types of X-ray imaging.

Claims 8-9, 12, and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) as applied to claims 6 and 7 above, and further in view of Jang (US 5757953).

Jang discloses an automated method and system of region decomposition in digital radiographic images. Jang teaches that shape filtering and connected component analysis are used to decompose an image into meaningful subregions (column 11, lines 30-67). The median filters can be used to smooth the image (column 9, line 3). The details of the operation of median filtering are old and well-known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a median filter and connected component analysis as taught by Jang, in the combined system of Mate et al. and Cosman. One of ordinary skill in the art would have used these techniques to divide the image into useful regions, and to find the location of the markers in the images. In addition, by determining the location of markers in the image, the user would know which objects are not markers. It would be obvious to one of ordinary skill in the art to make sure that these objects would then not be considered as markers, and would not be used for any further steps, such as during the alignment.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jang (US 5757953) as applied to claim 8 above, and further in view of Gerig et al. (US 5446548).

Gerig et al. disclose a patient positioning and monitoring system. Gerig et al. teach the use of an epipolar line constraint (column 5, lines 19-43). Such a technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used an epipolar line constraint technique as taught by Gerig et al. in the combined system of Mate et al., Cosman, and Jang. One of ordinary skill in the art would use such a technique to aid in aligning the markers in the sets of images.

Claims 15 and 63-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) as applied to claims 1 and 14 above, and further in view of Fitzpatrick et al. (US 6073044).

Fitzpatrick et al. disclose a method for determining the location in physical space of a point of a fiducial marker. Fitzpatrick et al. teach that a rigid body transform is necessary to register and align the coordinate systems of two imaging modalities (column 1, lines 42-58). A rigid body transform technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a rigid body transform technique as taught by

Fitzpatrick et al., in the combined system of Mate et al. and Cosman. When using two imaging modalities, such a technique will allow for the two imaging spaces to be properly registered and aligned, and thus the markers in the two images to be aligned. This will allow for the proper positioning adjustment to be determined and executed.

Claims 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Fitzpatrick et al. (US 6073044) as applied to claim 64 above, and further in view of Mansfield et al. (US 7227925).

Mansfield et al. disclose a gantry mounted stereoscopic imaging system. Mansfield et al. teach acquiring images from different angles and using them to reconstruct a stereoscopic image (column 7, lines 49-67). Also, the image angle can be the same as the treatment beam angle (column 6, lines 7-11).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have acquired images from different angles as taught by Mansfield et al. in the combined system of Mate et al. and Cosman. Acquiring an image from more than one angle provides additional data that can be used for three-dimensional reconstruction. If the images were acquired at the same angle, this would not be possible. Also, it would have been obvious to have used the same angle for image as for a treatment beam, as this will reduce the amount of time between acquiring images and moving the treatment system into the proper location, because it is already in the proper location. A shorter time between imaging and treatment will

prevent more motion from occurring in between, which would reduce the accuracy of the system.

Response to Arguments

Applicant's arguments with respect to claims 1-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737